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09/917,385	07/27/2001	Lisa A.G. Tweardy	1461-R-00	9974

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IP Department  
Schnader Harrison Segal & Lewis  
1600 Market Street, 36th Floor  
Philadelphia, PA 19103

EXAMINER

PHANIJPHAND, GWEN G

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/917,385

Applicant(s)

TWEARDY, LISA A.G.

Examiner

Gwen Phanijphand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/23/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**Response to Amendment**

***Claim Rejections – 35 U.S.C. 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14 and 15 claim an angle “between 30° and 50° and 50°”, which is indefinite. The examiner interprets the angle in claims 14 and 15 to be “between 30° and 50°”.

***Claim Rejections – 35 U.S.C. 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 3, 4, 6, 7, 8, 11, 12, and 14 are rejected under U.S.C. 103(a) as being unpatentable over Bremer, U.S. Patent No. 4,612,930 in view of U.S. Patent No. 6,387,129 B2 to Rieser et al.

Regarding claim 1, Bremer discloses in Figure 3 a skull pin, comprising a pin body and a pin tip formed from the insulator “crystal alumina ceramic material” (column 1, line 53), which protrudes from the proximal end of the pin body. Bremer further discloses in Fig. 3 the protruding portion consisting of a straight-sided portion (33) and a tapered portion (36), but does not disclose a rounded tip. A rounded tip is well-known in screws and pins. Rieser et al. disclose in Fig. 2 a rounded tip (col. 2, ll. Line 40). It is advantageous to have a rounded tip so that insertion into the bone is less abrasive. When a tip is pointed, the tip concentrates pressure at the end, which creates more force than a rounded tip during initial impact and can cause more damage. It would have been obvious to one having ordinary skill in the art at the time of the

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invention for the pin tip of Bremer to be rounded as in Rieser et al. so that the pin tip would be less abrasive during penetration and fixation of the skull.

Regarding claim 2, Bremer claims the insulating material being ceramic material (column1, lines 50-51).

Regarding claim 3, Bremer claims in column1, lines 50-51 an insulating material (ceramic material). This skull pin is used during imaging procedures (col. 1, ll. 46-49) and serves as an electrical insulator.

Regarding claim 4, Bremer discloses in Figure 3 a pin body (27) that includes a bore (29: col. 4, ll. 37-41) for receiving the pin tip (37).

Regarding claims 6 and 14, Bremer discloses in Figure 3 a pin tip that includes a tapered end (36) having an angle between 30° and 50°.

Regarding claim 7, Bremer discloses a kit comprising a halo (Figure1) and a skull pin (Figure 3, 25). The skull pin comprises a body (27) and an insert (32) formed from an insulating material ("ceramic": column1, lines 50-51) protruding from the distal end of the pin body. The ceramic material functions as an insulating material during skull fixation for imaging.

In Fig. 3, the protruding portion of the insert consists of a straight-sided portion (33) and a tapered portion (36). Bremer, however, does not disclose a rounded tip. A rounded tip is well-known in screws and pins. Rieser et al. disclose in Fig. 2 a rounded tip (col. 2, ll. Line 40). It is advantageous to have a rounded tip so that insertion into the bone is less abrasive. When a tip is pointed, the tip concentrates pressure at the end, which creates more force than a rounded tip and can cause more damage. It would have been obvious to one having ordinary skill in the art at the

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time of the invention for the pin tip of Bremer to be rounded as in Rieser et al. so that the pin tip would be less abrasive during fixation of the skull.

Regarding claim 8, Bremer discloses in column 1, lines 50-51 a skull pin, which has an insert formed from the insulating material ceramic.

Regarding claims 11 and 12, Bremer discloses in Fig. 3 the straight-sided portion (33) being cylindrical.

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer, U.S. Patent No. 4,612,930.

Regarding claim 5, Bremer shows a skull pin that is basically the same as that recited in claim 1 except that it has a pin body with a bore for receiving the pin tip as opposed to the pin tip with a bore for receiving the pin body as stated in claim 5. The reversal of the pin tip with a bore for receiving the pin body and pin body with a bore for receiving the pin tip is an obvious reversal of parts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a pin tip with a bore for receiving the pin body interchangeably with a pin body with a bore for receiving the pin tip, since it has been held that a mere reversal of essential working parts of a device involves only routine skill in the art.

3. Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer, U.S. Patent No. 4,612,930 in view of Birk et al., U.S. Patent No. 5,961,528 and further in view of Rieser et al., U.S. Patent No. 6,387,129 B2.

Regarding claim 9, Bremer discloses in Fig. 3 a skull pin wherein the skull pin comprises a pin body (27), an insert formed from an insulating material (ceramic) that protrudes from a distal end of the pin body (32), a straight-sided portion (33), and a tapered portion (36). Bremer,

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however, does not disclose a kit comprising skull tongs but states that, “ the skull pin may be used with a conventional halo...or with other skull fixation apparatus used in medical treatment or operative procedures” (column 1, lines 25-28). Skull tongs and halos are well known analogous devices for fixating the skull pins around a head. Birk et al. disclose a skull pin similar to that of Bremer and also include skull tongs (12) as depicted in Figure 2. Skull tongs are useful for supporting pins on both sides of the head. Bremer also does not disclose a rounded tip. Rieser et al. disclose a rounded tip, which is also well known for pins. It is advantageous to have a rounded tip since a rounded tip does not concentrate pressure at the very tip. If more pressure is concentrated at the point where the tip meets the skull, more damage may be caused. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the kit of Bremer to include skull tongs as in Birk et al. since tongs and halos are known alternate and analogous devices, aiding in supporting the skull pins in equidistance between the skull and the fixation device around the head. It would have been obvious to one having ordinary skill in the art at the time of the invention to have a rounded tip such as in Rieser et al. since a rounded pin tip would be less abrasive for fixating pins around of the skull.

Regarding claim 10, Bremer discloses in column 1, lines 50-51 the insulating material being ceramic.

Regarding claim 13, Bremer discloses in Fig. 3 the straight-sided portion (33) being cylindrical.

Regarding claim 15, Bremer discloses in Figure 3 a pin tip that includes a tapered end (36) having an angle between 30° and 50°.

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*Response to Arguments*

4. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection. In response to the amended claims that now claim that "the pin tip consists of a cylindrical portion having straight sides and a tapered portion", those claims have been rejected in view of U.S. Patent No. 4,612,930 to Bremer. In Fig. 3, Bremer discloses a cylindrical portion having straight sides (33) and a tapered portion (36). In response to the amended claims that now claim "a rounded tip", those claims are rejected in view of U.S. Patent No. 6,287,129 B2 to Rieser et al, wherein discloses a rounded pin tip.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijsphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP

January 10, 2002

Gwen Phanijsphand  
Patent Examiner  
Art Unit 3731



Michael J. Milano  
Supervisory Patent Examiner  
Technology Center 3700